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Balloon Dilation of Severe Aortic Stenosis in the Neonate: Comparison of Anterograde and Retrograde Catheter Approaches

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Objectives. **We sought to compare anterograde and retrograde balloon dilation of severe aortic valve stenosis in neonates.**

Background. **There is a high incidence of iliofemoral artery complications after retrograde balloon dilation of the aortic valve in the neonate. Therefore, a nonarterial technique of catheter access to the aortic valve would be worth exploring.**

Methods. **Group 1 included 11 consecutive patients (median age 6 days, range 1 to 42; median weight 3.5 kg, range 2.16 to 4.25) undergoing attempted anterograde dilation through a femoral venous approach. Group 2 included 15 patients (median age 3 days, range 1 to 35; median weight 3.4 kg, range 2.5 to 4.4 kg) who underwent attempted retrograde dilation, including 2 in whom attempted anterograde approach had failed.**

Results. **The valve was successfully crossed in 9 of 11 anterograde and 13 of 15 retrograde dilations. In both groups, the peak gradient across the valve decreased significantly (both $p = 0.001$). On echocardiography, the jet width of the aortic incompetence/annulus diameter ratio was 0.16 ± 0.08 (mean ± SD) after anterograde and 0.51 ± 0.24 after retrograde dilation ($p = 0.03$), possibly because of unrecognized valve leaflet perforation. Two patients in group 1 developed persistent, mild mitral insufficiency. Femoral artery thrombosis developed in one patient after anterograde dilation and in eight after retrograde dilation ($p = 0.03$).**

Conclusions. **This series demonstrates that an anterograde approach for balloon angioplasty of severe neonatal aortic valve stenosis is feasible, achieves good hemodynamic relief and lessens morbidity compared with retrograde arterial techniques.**

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Balloon dilation of the aortic valve was first described in 1984 (1) and has since been applied successfully to infants and children as an alternative to surgical valvotomy (2,3). In recent years, the technique has been used in neonates with severe or critical aortic valve stenosis, with results comparable to surgical approaches (4). The left heart has generally been approached through the femoral (4), umbilical (5) or right common carotid arteries (6,7). Femoral artery access in neonates carries the risk of damage to the vessel, resulting in thrombosis and potential limb complications (2,8). Additionally, it is often necessary to exchange or withdraw catheters, further increasing the possibility of damage to the arterial wall.

An anterograde approach from the femoral vein would eliminate the risk of arterial compromise and would be superior to the retrograde approach, provided that the procedure was as effective as retrograde access, could be performed quickly and was free from neurologic complications due to wire manipulation. Additional benefits of this approach could result from the wire reliably crossing the hemodynamic orifice of the valve rather than potentially piercing a valve leaflet, leading to severe aortic incompetence on dilation. To this end, encouraging experience with an anterograde approach was reported (9) in a group of nine children ranging in age from 1 day to 11 years. Reported here is our experience with an anterograde approach to aortic valve balloon dilation in a consecutive group of 11 neonates with severe aortic valve stenosis, with particular emphasis on technique and comparison of results in a similarly aged group undergoing dilation from the aorta.

Methods

Echocardiographic and clinical assessment. All patients underwent a complete two-dimensional echocardiographic study before intervention, including assessment of the ventricular morphology and the diameter (at the hinge points) of the mitral and aortic valves. In cases where the left ventricle did not reach the apex of the heart, a Rhodes score was calculated (10). Left ventricular ejection fraction was measured using a biplane Simpson method. *Severe aortic stenosis* was defined as an arterial duct-dependent systemic circulation, symptomatic heart failure or a derived peak to peak Doppler gradient >60 mm Hg (11). *Degree of aortic valve incompetence* was measured semiquantitatively, using the ratio of regurgitant jet width to annulus size (12). *Mitral valve incompetence* was assessed qualitatively by Doppler colorflow mapping and categorized as nil, trivial, mild, moderate or severe. In two of the

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earlier group 2 patients, Doppler color flow mapping of the mitral valve was not available. Unless otherwise stated, pressure gradients are those measured at cardiac catheterization. Echocardiography was repeated within 24 h of the procedure to assess function and the degree of aortic and mitral valve incompetence.

Patients. *Group 1.* Between November 1994 and November 1995, 11 consecutive neonates with severe aortic valve stenosis underwent attempted balloon dilation of the aortic valve using an anterograde catheter approach. There were nine male and two female neonates, and all but one was <28 days old (median age 6 days, range 1 to 42; median weight 3.5 kg, range 2.2 to 4.25). Four patients presented with congestive heart failure on day 1 of life; four had a murmur and congestive heart failure within the first week of life; and two had a murmur and congestive heart failure and presented at 2 weeks of life. The remaining patient, who presented with a murmur on day 1, remained well but developed an increasing aortic valve echocardiographic-Doppler gradient.

Six patients had a patent arterial duct: shunting was predominantly right to left in two and bidirectional in four. One patient had partial anomalous pulmonary venous drainage of the left upper pulmonary vein to the innominate vein, and two had mild hypoplasia of the aortic isthmus. Five patients had reduced left ventricular function (ejection fraction between 10% and 40%), and in four of these five patients, the mitral valve chordae and papillary muscle apparatus had a bright appearance on the echocardiogram, suggesting endocardial sclerosis. Three patients had hypoplasia of the left ventricle with a Rhodes score (10) of −0.14, +0.3 and +1.4, respectively; in another two patients, the left ventricle was dilated (end-diastolic dimension 2.2 and 2.3 cm, respectively, both above the 95th percentile for age).

Group 2. Between April 1985 and April 1995, 15 patients underwent attempted balloon dilation of the aortic valve from a retrograde catheter approach, including two who had an unsuccessful attempt using an anterograde approach (median 3 days, range 1 to 35; median weight 3.5 kg, range 2.5 to 4.4). Five patients presented with heart failure and poor perfusion on day 1 of life, three with heart failure within the first week and one each at 10 days, 14 days and 1 month. Three patients were found to have a murmur within the first few days of life that was diagnosed echocardiographically at 1, 6 and 20 days of age. One patient was diagnosed by fetal echocardiography and transferred to the catheter laboratory on day 1 of life while receiving a prostaglandin infusion. Of six patients with evidence of right to left shunting across a patent arterial duct, bidirectional shunting was present in one, and two had coarctation of the aorta. Three patients had hypoplastic left ventricles (end-diastolic dimension 0.7, 1.5 and 1.55 cm, respectively, all below the fifth percentile for age), and one had a dilated ventricle (end-diastolic dimension 2.53 cm). In six patients, an echo-bright appearance of the mitral valve chordae and papillary muscle apparatus suggested endocardial sclerosis. One patient had surgical open valvotomy on day 1 but required further intervention at 9 days.

Procedures. All procedures were performed under general anesthesia with mechanical ventilation.

Group 1. In the first patient, percutaneous entry was achieved from the right femoral vein and umbilical artery. After unsuccessful attempts to cross the valve from the ascending aorta, a 4F right coronary artery catheter (Judkins type, Cook) with a 2.5 curve was passed through the oval foramen and into the left ventricle. Counterclockwise rotation allowed the tip to turn toward the left ventricular outflow tract. A guide wire was passed across the aortic valve into the ascending aorta and snared (Amplatz, Cook) from the retrograde umbilical arterial catheter to stabilize its position. In the remaining cases, stable wire position was achieved from anterograde cannulation with no attempted retrograde approach. A 4F right coronary catheter (2.5 curve) was used to enter the left ventricle through the oval foramen in three cases, a 5F right coronary catheter (2.5 curve) in five cases and a 5F end-hole balloon catheter (Critikon, Inc., Ontario) in one case. In one patient, percutaneous entry into the femoral artery was performed for pressure monitoring. Pressures in the left ventricle and aorta were measured, and the aortic valve annulus diameter was measured from a left ventricular angiogram (n = 7) or ascending aortogram (n = 2) using the catheter diameter to correct for magnification. The initial guide wires used to cross the aortic valve included a 0.014-in. coronary wire (C.R. Bard Inc.) (n = 1), a 0.035-in. flexible tipped wire (Wholey, Mallinckrodt Medical) (n = 5), a 0.035- or 0.018-in. hydrophilic wire (Terumo Corp., Tokyo, Japan) (n = 2) or a 0.025-in. Teflon-coated wire (Cook Inc.) (n = 1). If possible, the wire was directed into the descending aorta; however, in four patients, the soft tip of the guide wire was left in the innominate artery for stability. The coronary catheter was curled in the left ventricle and then advanced over the wire to either the ascending or descending aorta, and the initial wire was exchanged for a 0.035-in. guide wire (Cook Inc.) (Fig. 1, left). A 2-cm long balloon (Cordis Corp.) with a diameter 90% to 100% of the estimated aortic annulus diameter was selected and advanced over the guide wire. Care was taken to position the balloon within the left ventricle distal to the mitral valve apparatus. After an inflation with dilute contrast medium (Fig. 1, right), the balloon was withdrawn and replaced with the right coronary catheter. Pressures in the left ventricle and aorta were remeasured, and the procedure was repeated if no change in gradient was documented. In four patients, the balloon size was increased by 1 mm and in one patient by 2 mm. Ventriculography was performed before and after the dilation to assess valve mobility, chamber function and mitral regurgitation.

Group 2. Retrograde balloon dilation was from an umbilical artery approach in one patient and through the femoral artery in the remaining 14. The aortic valve annulus diameter was estimated from an ascending aortogram, and the valve was dilated using the appropriate balloon diameter (see Procedures, Group 1) introduced over a guide wire whose tip was curled in the left ventricular apex. In two patients, the balloon

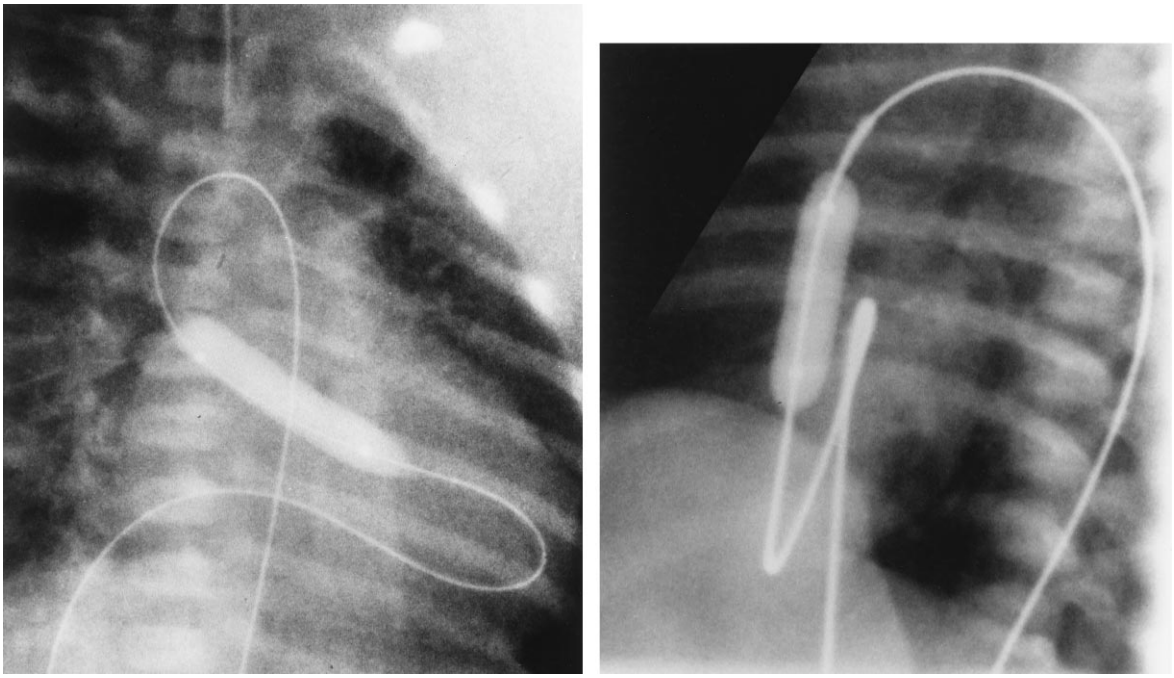

Figure 1. Left, Guide wire looped in the left ventricular apex, clear of the mitral valve apparatus, crossing the aortic valve and positioned in the descending aorta of a 3.8-kg neonate. **Right,** Balloon dilation of the aortic valve using a 6-mm × 2-cm balloon over a 0.035-in. wire, stabilized in the descending aorta. Inflation produced a decrease in peak systolic gradient from 100 to 26 mm Hg, with no residual aortic or mitral valve incompetence.

size was increased by 2 mm. Aortography was repeated to assess aortic valve mobility and degree of aortic regurgitation.

Statistics. Normally distributed continuous variables are presented as mean value ± SD and other variables as medians with ranges or frequencies. Between-group comparisons were made with a Student *t* test, chi-square with Fisher exact test or Mann-Whitney *U* test, depending on whether data was parametric or nonparametric. A p value <0.05 was considered significant.

Results

Group 1. Of the 11 attempted anterograde dilations, the aortic valve was successfully crossed in all but two patients. In the first of these, the balloon was successfully advanced across the valve but was poorly seated, and the dilation was ineffective; in the second, an anterograde approach was abandoned after the development of atrial flutter requiring overdrive pacing for termination. These two patients subsequently underwent retrograde dilation at the same catheterization and are included in group 2. Clinical and hemodynamic data for the remaining nine group 1 patients are presented in Table 1. The median balloon diameter was 6 mm (range 5 to 8), the mean ratio of balloon diameter to aortic annulus diameter was 1 ± 0.06, and the median fluoroscopy time was 40 min (range 22 to 63). Although ventricular ectopic activity was not uncommon, no additional prolonged or hemodynamically compromising rhythm disturbances occurred during wire, catheter or balloon manipulation. The initial and postprocedural peak to peak systolic gradients across the aortic valve were 62 ± 20 and 17 ± 5 mm Hg, respectively (p = 0.001). Left ventricular ejection fraction, as estimated by echocardiography, changed from a mean of 45 ± 21% (range 10% to 80%) to a mean of 55 ± 19% (range 22% to 86%) within 24 h of the procedure (p = 0.002). Of the four patients presenting with poor left ventricular performance, three had normal function by 4 months, and one continues to have poor function. This latter child developed a calculated peak to peak gradient by Doppler of 81 mm Hg and

Table 1. Group 1 (anterograde approach): Clinical and Hemodynamic Data

Pt No./ Age (days)	Wt (kg)	LVEF (%)		Annulus Diam (mm)	Balloon Size (mm)	Peak Systolic Gradient (mm Hg)	
		Pre	Post			Pre	Post
1/2	3.1	10	22	6	6	50	18
2/6	3.9	16	25	6	7	39	23
3/6	3.5	72	86	8	8	113	19
4/16	3.3	40	48	5	5	60	10
5/42	4.3	72	76	6	6	46	14
6/2	3.8	NA	NA	7	6	100	26
7/1	3.2	10	28	6	6	20	4
8/2	3.5	64	75	7	8	80	24
9/6	2.2	80	80	5	5	53	17

Diam = diameter; LVEF = left ventricular ejection fraction; NA = not available; Post = after the procedure; Pre = before the procedure; Pt = patient; Wt = weight.

had an uneventful surgical valvotomy at 4 months of age. One other patient with normalized left ventricular function has a Doppler peak to peak gradient of 56 mm Hg at 6 months after the procedure and is scheduled for reintervention.

Complications. Echocardiographically, of seven patients with no preexisting aortic incompetence, four developed mild insufficiency, the remaining three having none after the procedure. One patient with mild aortic incompetence before dilation had moderate incompetence after the procedure, and in one further patient the degree of regurgitation went from trivial to moderate. The ratio of regurgitant jet width to aortic annulus diameter increased from a mean of 0.03 to a mean of 0.16 ($p = 0.008$). From qualitative assessment using Doppler color flow mapping, the degree of mitral valve incompetence was unchanged in four patients, whereas in one it appeared to decrease from moderate to mild. In four patients the degree of mitral valve incompetence increased: Two developed mild and two moderate mitral regurgitation. In the latter two patients, the mitral regurgitant jet appeared to arise from the anterior mitral leaflet and may represent damage from the wire or balloon catheter. One patient was treated with afterload reduction and diuretic drugs, and in both patients the degree of mitral regurgitation decreased to mild within 1 week.

All femoral pulses were normal after catheterization, except in the one patient (11%) in whom a catheter had been placed in the femoral artery for pressure monitoring. Gradual resolution of the compromised pulse in this patient occurred after thrombolytic therapy. The smallest patient (2.2 kg) had echocardiographic evidence of a 1 cm × 0.4-cm thrombus within the left atrial appendage after the procedure and was treated uneventfully with low molecular weight heparin. There were no acute deaths or neurologic sequelae.

Group 2. In group 2, the valve could not be crossed in the first 2 patients, leaving 13 who underwent dilation. Clinical and hemodynamic data for group 2 patients are presented in Table 2 and are compared with those in group 1 patients in Table 3. The mean ratio of balloon diameter to aortic annulus diameter was 1 ± 0.06, and the median fluoroscopy time was 18 min (range 5 to 72). Fluoroscopy times are skewed by one of the unsuccessful anterograde dilation attempts. The initial and postprocedural peak to peak systolic gradients across the aortic valve were 52 ± 17 and 17 ± 5 mm Hg, respectively ($p = 0.001$). Measured left ventricular ejection fractions went from 53 ± 18% (range 10% to 79%) to 58 ± 12% (range 32% to 85%, $p = 0.1$).

Complications. There were six deaths after retrograde balloon dilation (mortality rate 46%). All deaths were related to the occurrence of severe ($n = 5$) or moderately severe ($n = 1$) aortic incompetence. Two patients underwent an emergent Ross procedure and one patient a Konno procedure 5 weeks after dilation. In the latter patient, complete detachment of an aortic valve leaflet was noted at operation. The degree of aortic incompetence was unchanged in four patients (nil in two, mild in two). In the remaining nine patients, all of whom had no incompetence before dilation, regurgitation increased and became severe in five and moderate in four. The ratio of regurgitant jet width to aortic annulus diameter increased from a mean of 0.02 to a mean of 0.51 ($p = 0.003$). Of the 11 patients in whom a qualitative assessment of mitral incompetence is available, 1 demonstrated a decrease from moderate to mild,

Table 2. Group 2 (retrograde approach): Clinical and Hemodynamic Data

Pt No./ Age (days)	Wt (kg)	LVEF (%) Pre	LVEF (%) Post	Annulus Diam (mm)	Balloon Size (mm)	Peak Systolic Gradient (mm Hg) Pre	Peak Systolic Gradient (mm Hg) Post
1/5	4.4	NA	NA	8	8	124	36
2*/1	3.2	NA	NA	6	6	5	0
3*/11	3.5	NA	NA	5	5	19	0
4*/2	2.7	NA	NA	6	4, 5, 6	20	14
5*/9	3.5	NA	67	7	7	63	20
6/3	3.5	78	78	6	6	50	20
7/25	3.0	79	85	8.8	8	54	14
8*/1	3.8	10	32	6	6, 8	49	7
9*/3	3.5	67	56	8	8	95	17
10/35	3.3	36	42	7	7	61	26
11/7	3.5	69	84	6.5	7	45	16
12*/1	2.9	54	NA	7.4	7	38	6
13/17	3.5	28	47	7	6	50	24

*Died. Abbreviations as in Table 1.

Table 3. Comparison of Anterograde and Retrograde Approaches to Aortic Valve Dilation in Neonates

	Group 1 (anterograde approach) (n = 9)	Group 2 (retrograde approach) (n = 13)	p Value
Age (days)			
Median	6	3	0.5
Range	1–42	1–35	
Wt (kg)			
Median	3.5	3.5	0.5
Range	2.2–4.25	2.5–4.4	
Before dilation			
Peak gradient (mm Hg)	62 ± 20	52 ± 17	0.44
LVEF (%)	45 ± 21	53 ± 18	0.6
AI ratio			
Median	0	0	0.5
Range	0–0.13	0–0.12	
Balloon/annulus ratio	1 ± 0.06	1 ± 0.06	0.64
Fluoroscopy (min)	43 ± 9	25 ± 10	0.03*
After dilation			
Peak gradient (mm Hg)	17 ± 5	17 ± 5.5	0.9
LVEF (%)	55 ± 19	58 ± 12	0.8
AI ratio	0.16 ± 0.08	0.51 ± 0.24	0.03*
Increase in MR	2	0	0.17
Arterial thrombosis	11%	62%	0.03*
Mortality rate	0%	46%	0.046*

*Significant at 5% level. Data presented are mean value ± SD, unless otherwise indicated. AI ratio = aortic regurgitant jet width/annulus ratio. Increase in MR = number of patients who went from mild or less to moderate mitral regurgitation or more; other abbreviations as in Table 1.

and 1 in whom anterograde dilation was attempted developed mild regurgitation after the procedure. In the remaining nine patients, the degree of mitral incompetence was unchanged.

Of eight patients who developed femoral artery thromboses (62%), one also had laceration of the femoral artery that required surgical repair. In one patient, pulse resolved with heparin therapy alone, and five underwent successful thrombolysis, leaving two lesions unresolved. Other complications included ventricular fibrillation during balloon inflation in one patient, which also produced a small tear in the ascending aorta and an episode of bacterial endocarditis in another patient. There were no acute neurologic events among survivors.

Comparison of groups 1 and 2 (Table 3). There were no significant differences between the two groups in age or weight at dilation, peak systolic pressure gradient, left ventricular ejection fraction or ratio of maximal balloon size to aortic valve annulus diameter before and after the procedure. Although the anterograde approach took significantly longer, the retrograde approach was associated with significantly higher mortality, an increased incidence of arterial complications and more severe aortic incompetence. There was no significant difference in degree of mitral regurgitation between the groups after the procedure.

Discussion

Mortality. The present series compares retrograde and anterograde catheter approaches for dilation of severe aortic valve stenosis in neonates. Not all patients had arterial duct-dependent systemic circulations; thus, the term "severe" is used in preference to "critical." Because the present trial was not a randomized, controlled one, the two groups are not strictly comparable, and several of the retrograde dilation attempts were performed early in the evolving experience of catheter-directed therapies. In addition, three earlier patients had qualitatively small ventricles, predating attempts to assess candidacy for biventricular repair (10) and may not have been suitable retrospectively for dilation. Because these three patients predated formal echocardiographic application of the scoring system described by Rhodes et al. (10), we were unable to retrospectively assign a reliable score and must accept this limitation of a retrospective control. Mortality rates from other series of retrograde balloon dilation of the aortic valve in the neonate range from 10% to 20% (4–6). In our experience, if patients who underwent angioplasty before 1990 are excluded (which includes those with unequivocally small ventricles), the mortality rate for the retrograde group was 33%. In addition, the incidence of predominantly right to left shunting at the ductal level was higher in the retrograde group. Although the high mortality for the retrograde group may be peculiar to the operators or technically related, as described later, the mortality is within the confidence limits of the published data, and all procedures were undertaken by one of two primary operators (D.N., L.B.), whether anterograde or retrograde. Nevertheless, the differences in mortality for the two approaches are striking, and several of the patients who died after an attempted retrograde approach had normal ventricular size and function.

Aortic incompetence. We believe that the major factor leading to a poor outcome after retrograde dilation is the development of severe aortic incompetence. A sudden volume load, together with reduced coronary perfusion in addition to the substrate of poor ventricular function or hypertrophy, can rapidly lead to hypotension and acidosis despite prompt resuscitative measures. Three patients with severe aortic incompetence died after cardiac catheterization: two died after emergency surgery; and one whose valve incompetence was slightly less severe (ratio of echocardiographic regurgitant jet width to aortic annulus diameter of 0.9) died after attempted repair at 5 weeks. These results emphasize the importance of avoiding acute severe aortic incompetence in infancy, a situation that can rarely be successfully salvaged in the operating room.

In contrast, only two patients developed moderate aortic incompetence after an anterograde approach, although the ratio of balloon to annulus diameter was the same for both groups. No patients died in this group. Crossing the aortic valve in an anterograde fashion allows the wire to be advanced through the hemodynamic valve orifice and, together with the use of floppy-tipped guide wires, can reduce the risk of valve leaflet perforation. We speculate that it is this inadvertent valve perforation and subsequent dilation that led to severe aortic incompetence (4) in the present series but emphasize that this group of patients reflects procedures undertaken early in the overall experience.

Mitral incompetence. There was no progression of mitral valve incompetence after the retrograde approach. However, after the anterograde approach, two patients developed moderate regurgitation, which appeared to improve with time. Nevertheless, the anterograde approach to the aortic valve for dilation does carry potential risks of damage to the mitral valve apparatus. The catheter and guide wire may pass between chordae, resulting in injury to the tension apparatus when the balloon is withdrawn. Such injury may be avoided by utilizing an end-hole balloon catheter to traverse the mitral valve in an effort to avoid the tension apparatus before achieving wire position. The total balloon length, including taper that is too long, may also cross and possibly damage the anterior mitral valve leaflet during inflation. Looping and hand shaping the guide wire toward the apex of the left ventricle may help to avoid the mitral tension apparatus and reduce the potential for the guide wire to simultaneously prop open both the mitral and aortic valves, resulting in a marked reduction in forward flow. Hypoplastic ventricles may be more prone to these events. Although echocardiography during the procedure may help to identify an improperly placed wire across the mitral valve, this is not our current practice in the catheterization laboratory.

Arterial complications. A significant difference in morbidity was seen in arterial complications. The incidence of femoral artery thrombosis was 62% (n = 8) when arterial access was used and only 11% (n = 1) with an anterograde approach. This latter case was early in the experience and was unrelated to the

technique. Previously reported series (2,8) also report a high incidence of arterial complications when the femoral artery was used for vascular access. No neurologic sequelae were seen after anterograde balloon dilation, although a thrombus within the left atrial appendage did develop in the smallest patient. This occurrence can be lessened by systemic heparinization. Avoidance of direct manipulation of the carotid artery removes the potential for acute and long-term neurologic sequelae due to vessel compromise.

In all but the first two attempted anterograde dilations, the valve was successfully crossed and dilated. Significant reductions in systolic pressure gradients were achieved with improvement in left ventricular function, when impaired. No deaths occurred, and there was a low incidence of mitral incompetence, only one arterial thrombosis and a single occurrence of thrombus in the left atrial appendage.

Conclusions. Compared with retrograde balloon dilation of the aortic valve, the anterograde approach has lower mortality and morbidity and should be the considered for neonates in the biventricular repair category.

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